

REMARKS

Amendments to the claims are for the purpose of clarifying what Applicant regards as the invention. Amendments to claim 3 are to bring it into conformity with the language in its corresponding independent claim. No new matter has been added. Because the amendment is submitted in the revised format, the current requirement in 37 C.F.R. 1.121(b) to provide a clean version of each replacement paragraph is believed waived.

Objections to the Drawings

According to the Office Action, drawing sheet nos. 1, 2, 5B, 6A, and 10 stand objected to as failing to meet the left margin requirement. The left margin of the drawing sheet nos. 1, 2, 5B, 6A, and 10 have been corrected in the formal drawings. It is believed that the formal drawings submitted herein obviate the objection to the drawings.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-29 and 43 stand rejected under 35 U.S.C. § 112, first paragraph. According to the Office Action, while the specification is enabling for a method of classifying a chromatogram, it does not reasonably provide enablement for all forms of the elements recited in the claims. Applicant respectfully submits that the enablement requirement of 35 U.S.C. § 112 is satisfied with respect to claims 1-29, 43, and new claims 44-56.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire

scope of the claim, the enablement requirement of 35 U.S.C. §112 is satisfied. M.P.E.P. § 2164.01(b). In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. Ex Parte Hitzeman, 9 USPQ2d 1821, 1823 (CCPA, 1987); and In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). For example, as a general rule, the claims to a mechanical invention can be framed as broadly as possible in light of the prior art, and such claims can be properly based on a disclosure in the specification of but a single embodiment. AMI Industries, Inc. v. EA Industries, Inc., 204 USPQ 568, 588 (1979). On the other hand, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement varies inversely with the degree of unpredictability of the factors involved. In re Fisher, Id. If one embodiment is disclosed in the specification, along with the general manner in which its current range was ascertained, the other permutations of the invention could be practiced by those skilled in the art without undue experimentation. U.S. v. Teletronics Inc., 8 USPQ2d 1217, 1223 (Fed. Cir., 1988). Here, Applicant's invention does not concern unpredictable factors such as a chemical reaction, a result of experiment in genetic engineering, or a physiological activity. Rather, Applicant's invention deals with methods of analyzing data, i.e, chromatogram data, which may be implemented using software, hardware, or combination of both, the nature of which is clearly very predictable. For example, each of the steps recited in claim 1 can clearly be practiced with predictable result. As such, Applicant respectfully requests that the claim rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-29 and 43 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicant believes that the amendments to claims 1, 3, 10, 12, 13, 19-21, and 43 have removed the alleged indefiniteness, and as such, respectfully requests the Examiner to withdraw the §112 rejections.

With respect to the rejection to claim 6, Applicant respectfully submits that this claim is definite. As described on page 6, lines 16-30 of the application, the term "bad data" refers to data that may be determined based on a threshold characteristic, such as a height, shape, size, position, and/or slope of a peak in a region of interest. The term, "threshold", which generally means a "boundary", or "a point or value above which something is true or will take place and below which it is not or will not (take place)" (See web page printout of Merriam-Webster On-Line Dictionary, a copy of which is attached herewith). As such, the term, "threshold" is not ambiguous, and is adequate for providing definiteness to claim 6. One of skill in the art would understand the meaning of "threshold" and be able to determine what it is in a particular application without undue experimentation. Furthermore, because several examples of "threshold characteristic" have been described in the specification, Applicant submits that claims are definite for this additional reason.

Claim Rejections under 35 U.S.C. § 102

Claims 1-29 and 43 stand rejected under 35 U.S.C. § 102 as being unpatentable over U.S. Patent No. 6,195,449 B1 issued to Bogden et al. ("Bogden"). Applicant respectfully notes that in order to sustain a rejection under §102, each element in the rejected claim must be found, either expressly or inherently, in the cited reference.

As amended, claims 1, 19, and 43 each recites the act of reducing chromatogram data to a

data set "based at least on an average time" for the chromatogram data in a region of interest. Bodgen does not disclose or suggest such limitation. Rather, Bodgen discloses a method for comparing chromatograms, which includes obtaining a gross alignment between a sample and a reference (as determined by comparison of base sequence between the sample and the reference), detecting peaks in the sample and reference, determining vectors for the peaks in the sample and the reference, and comparing vectors from the sample with vectors from the reference. (Column 10, line 45, to Column 14, line 27). There is nothing in Bodgen that discloses or suggests reducing chromatogram data to a data set based on an average time for the chromatogram data in a region of interest. Therefore, it is respectfully submitted that claims 1, 19, and 43 are believed allowable over Bodgen. For at least the same reason that claims 1 and 19 are allowable over Bodgen, claims 2-18, 44, and 45, which depend from claim 1, and claims 20-29, which depend from claim 19, are also believed allowable over the cited reference.

For at least this reason, Applicant submits that new claims 46-48 are allowable over Bodgen since these claims each recite "positioning the first region of interest based at least on an average time for the chromatogram data in the first region of interest", which as noted above, renders these claims allowable since Bodgen does not disclose or suggest positioning a region of interest based at least on an average time for the chromatogram data in a first region of interest.

New independent claims 49 and 54 each recites the act of positioning a first and second regions of interest without explicitly identifying a peak within the respective first and second regions of interest. Applicant also submits that new claims 49 and 54 are allowable over Bodgen for at least the reason that Bodgen does not disclose or suggest positioning a first and second regions of interest without explicitly identifying a peak within the respective first and second regions of interest. Rather, Bodgen discloses a method for comparing chromatograms, which requires peaks be detected.

(Column 10, lines 44, to Column 11, lines 62, and Figure 6). As such, Applicant respectfully submits that claims 49 and 54 are allowable over the Bodgen reference. For at least the same reason that claims 49 and 54 are allowable over Bodgen, claims 50-53, which depend from claims 49, and claims 55 and 56, which depend from claim 54, are also believed allowable over the cited reference.

Conclusion

Based on the foregoing, all remaining claims are believed allowable and a Notice of Allowance is respectfully requested. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at the number listed below.

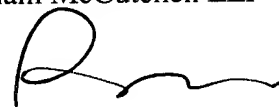
Respectfully submitted,

Bingham McCutchen LLP

Dated: _____

3-27-03

By: _____



Peter C. Mei
Reg. No. 39,768
(650) 849-4400

Varian, Inc.
Legal Department
3120 Hansen Way, D-102
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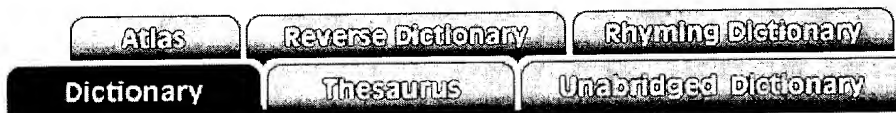


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One entry found for **threshold**.

Main Entry: **thresh·old** ˈ

Pronunciation: 'thresh-"hold, 'thre-"shold

Function: *noun*

Etymology: Middle English *threshold*, from Old English *threscwald*; akin to Old Norse *threskjoldr* threshold, Old English *threscan* to thresh

Date: before 12th century

1 : the plank, stone, or piece of timber that lies under a door : **SILL**

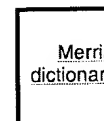
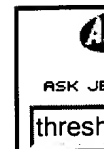
2 a : **GATE, DOOR** **b (1)** : **END, BOUNDARY**; *specifically* : the end of a runway **(2)** : the place or point of entering or beginning :

OUTSET <on the *threshold* of a new age>

3 a : the point at which a physiological or psychological effect begins to be produced **b** : a level, point, or value above which something is true or will take place and below which it is not or will not



thresh



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Pronunciation Symbols

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\&\ as e in <u>kitten</u>	\E\ as ea in <u>easy</u>	\oi\ as oy in <u>boy</u>
\&r\ as ur/er in <u>further</u>	\g\ as g in <u>go</u>	\th\ as th in <u>thin</u>
\a\ as a in <u>ash</u>	\i\ as i in <u>hit</u>	\th\ as th in <u>the</u>
\A\ as a in <u>ace</u>	\I\ as i in <u>ice</u>	\ü\ as oo in <u>loot</u>
\ä\ as o in <u>mop</u>	\j\ as j in <u>job</u>	\u\ as oo in <u>foot</u>
\au\ as ou in <u>out</u>	\[ng]\ as ng in <u>sing</u>	\y\ as y in <u>yet</u>
\ch\ as ch in <u>chin</u>	\O\ as o in <u>go</u>	\zh\ as si in <u>vision</u>

For more information see the [Guide To Pronunciation](#).

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